1. (Amended) A pharmaceutical composition comprising a solid dispersion of fenofibrate, or a salt or ester thereof, and polyvinylpyrrolidone (PVP) crystallization inhibitor in a polyethylene glycol (PEG) carrier.

13. (Amended) A method of preparing a composition of Claim 1, comprising the steps of:

a) dissolving a pharmaceutical compound and polyvinylpyrrolidone in an organic solvent to form a solution;

b) adding polyethylene glycol to said solution to form a mixture;

c) optionally flash evaporating said solvent;

d) optionally drying the resulting residue remaining after evaporation;

e) optionally grinding and sieving the solid dispersion to obtain a resultant product.

REMARKS

Claims 1-23 are pending in the application. Claims 1, 2, 8-10, 13-15, 18 and 19 stand rejected under 35 U.S.C. § 102(b), or alternatively under Claims 1-19 stand rejected 35 U.S.C. § 103(a), in view of the U.S. Patent No. 5,773,025 to Baichwal (hereinafter "the '025 patent"). Claims 1-23 stand rejected under 35 U.S.C. § 103(a) in view of the '025 patent and the PDR. Applicants respectfully traverse the rejections and request reconsideration thereof.

Restriction/Election Requirement

Applicants respectfully elect the invention directed to fenofibrate for search purposes. Claims 1-23 have been amended to delete non-elected subject matter. Claims 1, 4, 8-10, 13-15, 18, and 22 remain pending. Claims 2-3, 5-7, 11-12, 17, 19-21, and 23 have been cancelled. It is respectfully submitted that the pending claims, as amended, are directed to the subject matter elected for prosecution.

Rejection under 35 U.S.C. § 102(b)/§ 103(a)

Claims 1, 2, 8-10, 13-15, 18 and 19 stand rejected under 35 U.S.C. 102(b). Claims 2 and 19 have been cancelled. Claims 1, 8-10, 13-15, and 18 are directed to a pharmaceutical composition comprising a solid dispersion of fenofibrate, or a salt or ester thereof, and polyvinylpyrrolidone (PVP) crystallization inhibitor in a polyethylene glycol (PEG) carrier, specific capsule and tablet embodiments thereof, and processes for preparing the pharmaceutical composition. Applicants respectfully submit that the incorporation of PVP into a PEG carrier has not previously been recognized in the art, particularly with respect to a pharmaceutical composition comprising fenofibrate.

U.S. Patent No. 5,773,025 to Baichwal describes solid dosage formulation of an amorphous medicament. There is no appreciation or description that polyvinylpyrrolidone can be included in the formulation. Moreover, the '025 patent fails to teach, describe, disclose, or appreciate that any formulation comprising polyvinylpyrrolidone can be included in the preparation of a solid dosage form comprising a polyethylene glycol carrier.

In order to anticipate the invention under 35 U.S.C.§ 102(b), the cited reference must describe each and every element of the claimed invention. The '025 patent neither teaches, describes, discloses, nor appreciates that polyvinylpyrrolidone can be incorporated into a solid dosage form to provide a stable solid dispersion for fenofibrate, and particularly a stable solid dispersion in a hard gelatin capsule or tablet. In addition, the '025 patent teaches mixing PEG and water to form a slurry for preparing dosage forms. See, the '025 patent, column 14, lines 34-37. In contrast, the claimed invention, for example as specifically claimed in claims 1 and 13, incorporates PVP into a PEG carrier for an amorphous medicament, such as fenofibrate, which stabilizes the medicament to provide a suitable pharmaceutical solid dispersion dosage form. Such phenomenon is evidenced at least in the Figures 8-11 in the instant application, which indicate that PVP incorporated within a hydrophilic PEG matrix inhibits the crystallization of fenofibrate.

Claims 1-19 further stand rejected in view of Baichwal under 35 U.S.C. § 103(a) and Claims 1-23 further stand rejected in view of Baichwal and the PDR. Claims 2-3, 5-7, 11-12, 17, 19-21, and 23 have been cancelled. Applicants respectfully submit that the invention amounts to more than a mere substitution of medicament into a known formulation. Claims 1, 4, 8-10, 13-16, and 18 are directed to a solid dispersion incorporating polyvinylpyrrolidone, which improves the dissolution of the medicament, more particularly fenofibrate, and processes for preparing the compositions thereof. Claim 22 is directed to a method for using the claimed composition. Baichwal fails to teach, describe, or suggest that polyvinylpyrrolidone can be incorporated into the dosage form of the '025 patent. There is no teaching or suggestion that polyvinylpyrrolidone can be used as a crystallization inhibitor in a fenofibrate formulation or how to use such a formulation. One with skill in the art at the time of the invention would not be motivated to prepare the invention as claimed in view of the '025 patent, either with or without the contemplation of contents of the PDR.

Accordingly, Applicants respectfully submit that the application is in a condition for allowance and respectfully request notification of the same.

Objection to the Drawings

The drawings have been objected to for the reasons stated in the Form PTO-948. Applicants respectfully submit that formal drawings for the application will be provided in due course.

CONCLUSION

The Examiner is respectfully invited to contact the undersigned by telephone at the phone number provided below if doing so would further facilitate the prosecution of the application. A version of the amendments with markings to show changes made is attached herewith for the convenience of the Patent Office.

Respectfully submitted,
S. Krill, *et al.*

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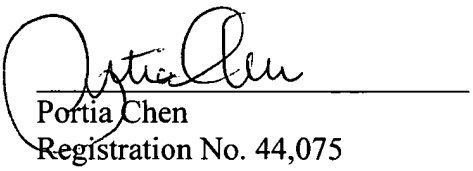

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Version with Markings to Show Changes Made

Claim 1. (Amended) A pharmaceutical composition comprising a solid dispersion of ~~a pharmaceutical compound~~ **fenofibrate, or a salt or ester thereof, and polyvinylpyrrolidone (PVP) crystallization inhibitor in** a ~~water soluble carrier~~ **polyethylene glycol (PEG) carrier.,** ~~and a crystallization inhibitor selected from the group consisting of polyvinylpyrrolidone (PVP) and hydroxypropylcellulose (HPMC).~~

Cancel Claims 2-3, 5-7, and 11-12.

Claim 13. (Amended) A method of preparing a composition of Claim 1**, comprising the steps of:** ~~which comprises:~~

a) dissolving a pharmaceutical compound **and polyvinylpyrrolidone in** ~~inhibitor into~~ an organic solvent to form a solution;

b) adding **polyethylene glycol** ~~a water soluble carrier~~ to said solution to form a mixture;

~~c) adding PVP to said mixture of step b);~~

~~d)~~ **c)** optionally flash evaporating said solvent;

~~e)~~ **d)** optionally drying the resulting residue remaining after evaporation;

~~f)~~ **e)** optionally grinding and sieving the solid dispersion to obtain a resultant product.

Cancel Claims 16-17, 19, 20-21, and 23.